REMARKS

Status of Claims:

Claims 1-50 are present for examination.

Claim Rejections:

Claims 1-4, 6, 8, 9, 12, 26, 28, 30, 31, 42, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulman et al. (U.S. Patent No. 6,164,284) (hereinafter Schulman).

Claims 5, 7, 10, 11, 13-25, 27, 29, 32-41, and 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman.

With regard to claims 1-50, the rejections are respectfully traversed.

Independent claim 1 recites a method of sensing multiple parameters comprising:

> "implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, each sensing element is operable through electrical communication with an external controller via an individual interconnect; and
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> reading an output from at least one of the implantable sensing elements,
>
> wherein a plurality of parameters are read from the implantable sensor at the single site, and
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> wherein the output read from at least one of the implantable sensing elements is a quantifiable value." (Emphasis Added).

A method including the above-quoted features has at least the advantages that an implantable sensor is implanted at a single site in a patient, where (i) the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements; and (ii) each

sensing element is operable through electrical communication with an external controller via an individual interconnect. (Specification; paragraph [0037]; Fig. 2, references 34, 32a-e, and 38).

Schulman neither discloses nor suggests a method including the above-quoted features including "implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, each sensing element is operable through electrical communication with an external controller via an individual interconnect".

The Examiner points to: (i) the sensor 100c of Schulman as disclosing an implantable sensor at a single site in a patient; (ii) column 4, lines 29-30, of Schulman as disclosing the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements; and (iii) figs. 2 and 3A, elements 172 and 174, column 7, lines 30-31, and column 15, lines 14-16 of Schulman as disclosing "each sensing element is operable through electrical communication with an external controller via an individual interconnect". (Office Action; page 2).

However, it is important to understand that each implanted device 100 of Schulman that may be a sensor 100c has its own housing, and Schulman neither discloses nor suggests disposing a plurality of the sensors 100c within a single housing. (Schulman; Fig. 1, references 100a-d; Fig. 8, references SE_1, SE_2, and SE_3; col. 4, lines 1-9). This is apparent from Fig. 1 of Schulman, where a single sensor 100c has its own housing, and there are not a plurality of the sensors 100c in a single housing. (Schulman; Fig. 1, reference 100c).

Also, it is important to correctly interpret the disclosure at column 4, lines 29-32, of the Schulman reference. In column 4, lines 29-32, Schulman states the following: "Preferably, these stimulators, sensors and transponders are contained in sealed elongate housing having an axial dimension of less than 60 mm and a lateral dimension of less than 6 mm." In the quoted portion of the Schulman reference, Schulman is explaining that each sensor 100c has its own sealed elongate housing. (Schulman; Fig. 1; Fig. 8; col. 4, lines 1-36). It is important to understand that

in the quoted portion of the Schulman reference, Schulman is not disclosing that a plurality of the sensors 100c are included in a single housing. This is apparent, because each sensor 100c in the system of Schulman is a type of implanted device 100 that has its own housing and that is positioned beneath the skin of a patient separate from other ones of the sensor 100c. (Schulman; Fig. 1, references 100a-d, Fig. 8, references SE_1, SE_2, and SE_3; col. 4, lines 1-10 and lines 32-37).

Furthermore, Fig. 3A of Schulman illustrates a block diagram of an implanted device, such as a sensor 100c, and Fig. 3A does not disclose or suggest a plurality of sensing elements disposed within a housing that are each individually connected to an external controller. (Schulman; Fig. 3A). Rather, the sensor 100c of Fig. 3A of Schulman only has one transmitter 168 and one receiver 114b, so it would be impossible to have individual connections for each of a plurality of sensing elements. (Schulman; Fig. 3A).

As a consequence, Schulman neither discloses nor suggests the claimed feature of "implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements, each sensing element is operable through electrical communication with an external controller via an individual interconnect".

Therefore, independent claim 1 is neither disclosed nor suggested by the Schulman reference and, hence, is believed to be allowable.

Because they depend from independent claim 1, dependent claims 2-25 and 49 are believed to be allowable for at least the same reasons that independent claim 1 is believed to be allowable. With regard to dependent claims 5, 7, 10, 11, and 13-25, which were rejected under 35 U.S.C. 103, it is further noted that the Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103.

Independent claim 26 recites a method with features similar to features of a method of independent claim 1 and, thus, is believed to be allowable for at least the same reasons that

independent claim 1 is believed to be allowable. Because they depend from independent claim 26, dependent claims 27-41 and 50 are believed to be allowable for at least the same reasons that independent claim 26 is believed to be allowable. With regard to dependent claims 27, 29, and 32-41, which were rejected under 35 U.S.C. 103, it is further noted that the Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103.

Independent claim 42 recites a method of sensing multiple parameters comprising:

> "implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements; and
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> reading an output from at least one of the implantable sensing elements,
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> wherein each of the plurality of implantable sensing elements comprises a power supply,
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> wherein a plurality of parameters are read from the implantable sensor at the single site, and
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> wherein the output read from at least one of the implantable sensing elements is a quantifiable value." (Emphasis Added).

A method including the above-quoted features has at least the advantages that an implantable sensor is implanted at a single site in a patient, where (i) the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements; and (ii) each of the plurality of implantable sensing elements comprises a power supply. (Specification; paragraph [0032]).

Schulman neither discloses nor suggests a method including the above-quoted features including "implanting an implantable sensor at a single site in a patient, the implantable sensor

having a housing within which are disposed a plurality of implantable sensing elements", wherein "each of the plurality of implantable sensing elements comprises a power supply".

The Examiner points to Schulman, column 15, lines 5-7, as disclosing that each of a plurality of implantable sensing elements comprises a power supply. (Office Action; page 3). However, it is important to note that the present claim 42 has the feature that the plurality of implantable sensing elements are disposed within a housing. Column 15, lines 4-7, of the Schulman reference states the following: "Accordingly, a preferred embodiment of the present invention is comprised of an implanted SCU 302 and a plurality of implanted devices 100, each of which contains its own rechargeable battery 104." (Emphasis Added).

In the cited portion of the Schulman reference, Schulman discloses that each implanted device 100 contains its own rechargeable battery 104. (Schulman; col. 15, lines 4-7). However, it is important to understand that Schulman does not provide for a plurality of implanted devices 100 to be disposed within a single housing. (Schulman; Fig. 1; col. 4, lines 1-10). Rather, each implanted device 100 in the system of Schulman has its own housing and is positioned beneath the skin of a patient separate from other ones of the implanted device 100. (Schulman; Fig. 1; col. 4, lines 1-10). Moreover, as is illustrated in Fig. 3A of Schulman, each implanted device 100 only has one power supply, so Schulman neither discloses nor suggests a plurality of sensing elements disposed within a housing where each of the plurality of sensing elements comprises a power supply. (Schulman; Fig. 3A).

Therefore, independent claim 42 is neither disclosed nor suggested by the Schulman reference and, hence, is believed to be allowable.

Independent claim 43 recites a method of sensing multiple parameters comprising:

> "implanting an implantable sensor at a single site in a patient, the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements; and

reading an output from at least one of the implantable sensing elements,

wherein a plurality of parameters are read from the implantable sensor at the single site,

wherein the output read from at least one of the implantable sensing elements is a quantifiable value, and

wherein the plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level, a blood oxygen saturation sensing element measuring a parameter for blood oxygen level, and a pH level sensing element measuring a parameter for pH level." (Emphasis Added).

A method including the above-quoted features has at least the advantages that an implantable sensor is implanted at a single site in a patient, where (i) the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements; and (ii) the plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level, a blood oxygen saturation sensing element measuring a parameter for blood oxygen level, and a pH level sensing element measuring a parameter for pH level. (Specification; paragraphs [0053]-[0055]).

Applicant has shown in the specification as filed, and in the previous response filed March 29, 2006, that the specific combination of a lactate sensing element, a blood oxygen saturation sensing element, and a pH level sensing element has advantages over the prior art. (Specification; paragraphs [0053]-[0055]). For example, in some embodiments, lactate levels, blood oxygen saturation, and pH levels may be monitored in connection with an implantable cardiovascular defibrillator (ICD) in a patient. (Specification; paragraph [0053]). In such embodiments, the placement of the ICD may be adjusted if a medical professional determines that, given the frequency and levels of electrical shocks generated by the ICD relative to lactate

levels, blood oxygen saturation, and blood pH, a more advantageous position within the patient is desireable. (Specification; paragraph [0054]).

Schulman neither discloses nor suggests a method including the above-quoted features including implanting an implantable sensor at a single site in a patient, where the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements, and where the plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level, a blood oxygen saturation sensing element measuring a parameter for blood oxygen level, and a pH level sensing element measuring a parameter for pH level.

As acknowledged by the Examiner, "Schulman et al. do not disclose a plurality of implantable sensing elements comprises a lactate sensing element measuring a parameter for blood lactate level and a pH level sensing element measuring a parameter for pH level." (Office Action; page 4) (Emphasis Added). The Examiner then states that "it is well known in the art for a plurality of implantable sensing elements to comprise a lactate sensing element measuring a parameter for blood lactate level and a pH level sensing element measuring a parameter for pH level". (Office Action; page 4).

However, the Examiner's failure to cite any prior art that shows the specific combination of sensors and the benefits provided by sensing the combination of parameters, demonstrates that such a combination of a lactate sensing element, a blood oxygen saturation sensing element, and a pH level sensing element is not obvious based on the prior art. The Schulman reference does not disclose or suggest that sensing the specific combination of parameters in a patient provides any useful benefit. Thus, the Examiner has merely provided conclusory statements with no prior art citations and no *prima facie* case of obviousness. In contrast, applicant has shown in the specification that the specific combination has advantages over the prior art.

Therefore, independent claim 43 is neither disclosed nor suggested by the Schulman reference and, hence, is believed to be allowable. The Patent Office has not made out a *prima facie* case of obviousness under 35 U.S.C. 103.

Because they depend from independent claim 43, dependent claims 44-48 are believed to be allowable for at least the same reasons that independent claim 43 is believed to be allowable.

Conclusion:

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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